

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION**

IAN WALLACE,

Plaintiff,

VS.

PHARMA MEDICA RESEARCH, INC.,

Defendant.

Cause No. 4:18-cv-01859-PLC

DEFENDANT PHARMA MEDICA RESEARCH, INC.'S
TRIAL BRIEF

COMES NOW, Defendant Pharma Medica Research, Inc. (“PMR”), by and through their counsel Hinshaw & Culbertson LLP, Terese A. Drew, and Angela S. McQuage, and for their Trial Brief, states as follows:

Trial Brief

Introduction

Plaintiff filed this case asserting theories of negligence and *res ipsa loquitor*. Plaintiff alleges PMR was negligent with regard to the manner in which the medical studies that Plaintiff participated in were conducted, and as a result of that negligence Plaintiff contracted Hepatitis C. Plaintiff participated in two medical studies with PMR in 2016. Plaintiff presented to Anderson Hospital on June 25, 2016 where he was diagnosed with acute Hepatitis C.

The following are potential legal issues this Court may encounter in this case:

I. Negligence

To establish a claim for negligence under Missouri law, the Plaintiff must prove: (1) the existence of a duty on the part of the defendant to protect the Plaintiff from injury, (2) a failure of

the defendant to perform that duty, and (3) an injury proximately caused by the defendant's failure. *Blevens v. Holcomb*, 469 F.3d 692, 694 (8th Cir. 2006).

A. Breach

There is no evidence that would support the conclusion that there was any breach of duty on the part of PMR. A defendant breaches its duty when it "fail[s] to exercise reasonable care to perform [its] undertaking. *Tharp v. St. Luke's Surgicenter-Lee's Summit, LLC*, 587 S.W.3d 647, 655 (Mo. 2019). The common law ordinary negligence rule requires a defendant to exercise the degree of care of a reasonable person of ordinary prudence under similar circumstances. *Id.*

There is no evidence that PMR breached any duty owed to Plaintiff. Plaintiff alleges PMR failed to properly train its employees and/or agents to perform blood extraction in a safe and sanitary fashion; failed to properly screen its employees and/or agents to ascertain whether said employees and/or agents were qualified and properly trained to draw blood samples in a safe and sanitary fashion, failed to properly supervise its employees and/or agents to insure that those employees and/or agents drew blood in a safe and sanitary fashion, failed to supply sufficient equipment to allow for the safe and sanitary drawings of blood samples, failed to properly clean and sterilize equipment used to draw blood samples, failed to properly screen its employees, and/or agents, and/or other participants in the study to determine whether such individuals were infected with contagious diseases; and failed to properly dispose of unsanitary equipment used in the blood drawing process. See, Plaintiff's Second Amended Complaint. However, there is zero evidence that Defendant actually failed to do any of the above. Plaintiff relies on Dr. Harry Hull's speculation that Plaintiff contracted Hepatitis C through a used/dirty needle stick during a PMR study. However, Plaintiff has no proof that the source of his acute Hepatitis C infection was PMR.

Defendant's expert Nancy Erickson PBT opines that a venipuncture needle from PMR did not cause Plaintiff's acute Hepatitis C infection. (See Report of Nancy Erickson PBT (ASCP) attached hereto as Exhibit A). Nurse Erickson testified it would be very difficult for a phlebotomist to have stuck Wallace with a dirty needle. For Plaintiff to have been stuck with a re-used, dirty needle, the phlebotomist would have had to prepare a needle prior to Plaintiff being primed for his blood draw and must have used this needle on a previous participant. (*Id.*) The safety needles used in these studies, a BD Vacutainer Eclipse Blood Collection needle with a Pre-Attached Holder, prevent a phlebotomist from reusing a needle. (*Id.*) The needles are sterile until opened, are always opened in front of the patient, a phlebotomist then would assemble the needle, that contained a safety shield for the protection of the clinical participant and the phlebotomist, stick the patient, perform a collection, activate the pink safety shield and dispose of it in a sharps container. (Exhibit A; Deposition of Nancy Erickson, p. 17-18, l. 22-5 attached hereto as Exhibit B). This safety action is muscle memory and it would take several, "calculated" actions to vary from that protocol. (Exhibit A).

She further testifies that it would be impossible to reuse a dirty needle. As soon as the needle comes out of the patient's arm, the medical professional activates the safety and would never be able to reuse the needle. (Exhibit B, p. 32, l. 21-25). Additionally, a needle could not be reused because the bore of the needle would get clogged with skin, tissue and blood. (Exhibit A; Exhibit B, p. 34, l. 2-23).

PMR representatives, Dr. Heather Jordan and Dr. Shabaz Khan, both testified that the safety precautions used at PMR would prevent a dirty needle stick. (Exhibit B, p. 9-10, l. 22-9). Further, neither Dr. Jordan, who was present on site, nor Dr. Khan was ever alerted to a dirty needle stick in either study. (Exhibit B, p. 56, l. 21-24; p. 57-58, l. 6-1).

Dr. Heather Jordan, the principal investigator at the St. Charles PMR facility, testified PMR had onsite training for phlebotomists and interns including on-site universal precautions training, and the blood-borne pathogens training. (Exhibit B, p. 46-47, l. 24-3). She also confirmed PMR used standard precautions including wearing gloves and using new needles. (Exhibit B, p. 9, l. 22-24; p. 10, l. 4-9). Dr. Jordan testified that she was physically on site at the facility and never heard of someone sticking a participant with a needle and then using the same needle on another participant. (Exhibit B, p. 56, l. 21-24; p. 57-58, l. 1). Also, she was never alerted to someone attempting to use the same needle on two participants. (Exhibit B, p. 57-58, l. 6-1). Additionally, Dr. Jordan testified there were supervisors present, including group leaders, a study coordinator, and quality control to confirm blood draws were being performed appropriately. (Exhibit B, p. 126, l. 5-10; 14-16).

Dr. Shabaz Kahn, the Vice-President of clinical operations at PMR, testified the clinic was well organized and they had quality control on-site to ensure procedures were being followed. (See Deposition of Dr. Shabaz Khan, p. 24, l. 10-24 attached hereto as Exhibit C). Dr. Kahn testified all blood draws were conducted in full light, with staff supervision, and universal precautions. (Exhibit C, p. 23, l. 2-24). He further testified that all used needles were discarded immediately and needles were never left exposed with the cap off. (Exhibit C, p. 26, l. 2-5, 7-10; p. 45, l. 9-14). Dr. Khan also testified there was always two staff members present during blood sample collection and there was always a supervisor on site, including a group leader, and a quality control associate study associate study coordinator or medic. (Exhibit C, p. 41, l. 9-11, 13-14, 16, 21).

Finally, Plaintiff has no direct knowledge of an actual dirty needle stick. Plaintiff testified he generally watched the blood draws and did not recall ever having any issues with a blood draw at PMR. (Deposition of Ian Wallace, p. 68, l. 1-4 attached hereto as Exhibit D). He testified he

never saw a phlebotomist (or other medical professional) at PMR use or stick him with a dirty/used needle. (Exhibit D, p. 181, l. 5-9). Plaintiff's brother, Cody Wallace, also testified that he never saw a phlebotomist (or other medical professional) at PMR use or stick Plaintiff with a dirty/used needle.

Nurse Erickson testified it would be near impossible for Plaintiff to have been stuck with a dirty needle, due to the safety needle and universal precautions utilized. Additionally, Dr. Jordan and Dr. Khan testified PMR phlebotomists received adequate training and there was extensive supervision to prevent any issues with blood draws. Finally, Plaintiff has no evidence that anyone actually witnessed Plaintiff stuck with a dirty needle. There is no evidence that PMR did not utilize ordinary care with regard to their employees/phlebotomists/interns, training, or blood draw techniques. As such, there is insufficient evidence to establish a breach.

B. Causation

To establish a claim for negligence, Plaintiff must prove causation. *Blevens v. Holcomb*, 469 F.3d 692, 694 (8th Cir. 2006). In order to prove a causal connection between an alleged negligent act and an injury requires the Plaintiff to show two things: (1) causation in fact and (2) proximate cause. *Bond v. Cal. Comp. & Fire Co.*, 963 S.W.2d 692, 697 (Mo. App. 1998). The test for causation in fact is the "but for" test. *Id.* The "but for" test for causation provides that "the defendant's conduct is a cause of the event if the event would not have occurred 'but for' that conduct." *Id.*(citations omitted). The but for test for causation applies to all cases, except those involving two independent torts, each of which is sufficient by itself to cause the injury. *Id.* "Evidence of causation must be based on probative facts not on mere speculation or conjecture..." *Id.*(citations omitted). The burden of establishing causation can be met by circumstantial evidence. *Id.*

"An inference is a logical *a priori* conclusion drawn by reason from proven or admitted facts. It is more than, and cannot be predicated on, mere surmise or conjecture. It is not a possibility that a thing could have happened or an idea founded on the probability that a thing may have occurred. *Bond*, 963 S.W.2d at 698.

The general test for proximate cause is whether an injury is the natural and probable consequence of the defendant's negligence. *Stanley v. City of Indep.*, 995 S.W.2d 485, 488 (Mo. 1999). Each case is decided on its own facts. *Id.* Proximate cause cannot be based on pure speculation and conjecture. *Id.*

"The usual test for a causal connection between a defendant's negligence and a Plaintiff's injury is whether the facts in evidence show that the injury would not have been sustained but for the negligence." *Delisi v. St. Luke's Episcopal-Presbyterian Hosp., Inc.*, 701 S.W.2d 170, 175 (Mo App. E.D. 1985). Causation requires not only proximity in time, but also a showing that Plaintiff would not have been injured but for defendant's negligence. *Id.* at 176.

As detailed above, the only evidence Plaintiff has to show PMR was negligent is Dr. Hull's opinion that more likely than not Plaintiff contracted Hepatitis C from a dirty needle stick at a PMR study. From such evidence, a reasonable jury could not infer that "but for" PMR Plaintiff would not have contracted Hepatitis C.

In addition to the needle sticks at PMR, there are several other possible causes of Hepatitis C including intravenous drug use, blood transfusions, needlesticks in health care settings, piercings and tattoos, sexually transmission and sharing razors/toothbrushes with a Hepatitis C positive individuals.

In addition to the latter, Plaintiff participated in two (2) other studies with needlesticks (Spaulding and BioPharma). In February 2016 Plaintiff participated in a study with BioPharma.

(Exhibit D, p 40, l 2-12). For that study, Plaintiff underwent multiple blood draws. (Exhibit D, p 40, l 13-24). Plaintiff also was screened for a study with Spaulding on May 18, 2016 and May 22, 2016. (Exhibit D, p. 43, l. 8-21). Plaintiff did not complete the study as they were not used as subjects, however, he did undergo two (2) blood draws. (Exhibit D, p. 43, l. 22-23).

The only evidence of Plaintiff's lack of piercings and tattoos is solely Plaintiff's testimony. Despite a medical examination, Dr. Hull failed to visually confirm that Plaintiff did not have any piercings or tattoos. (See Deposition of Dr. Hull, p. 30, l. 15-18 attached hereto as Exhibit E). Although, Plaintiff claims his girlfriend at the time tested negative for Hepatitis C, she has only been tested once. As described above, it is possible for someone to be positive for Hepatitis C but test negative. Plaintiff claims since he never failed a drug test for a medical study, he could not have contracted Hepatitis C through drug use. (Exhibit D, p. 183, l. 16-17). However, Plaintiff could have partook in intravenous drug use during a time that he did not undergo a drug test. Further, it's possible he could have been positive for Hepatitis C but did not have enough antibodies to trigger a positive test.

Again, Plaintiff did not see anyone use a dirty/used needle during any of his blood draws. A blood draw is not a subtle process. It requires a needle being inserted into a vein to draw blood. Typically a blood draw results in bleeding or bruising. If there is a complicated blood draw, such as with a dirty/used needle, one would become aware of the issue. As Nurse Erickson testified, once a needle is used the safety is engaged and it would be impossible to use that particular needle again (Exhibit A). If a medical professional attempted to use a needle that had already had the safety engaged, it would be noticed by the individual. Further, once the needle has been used, blood and tissue collect inside the needle which would cause issues with another attempted blood draw (Exhibit A). As someone who experienced a high number of blood draws, Plaintiff would

have recognized an abnormal blood draw. Plaintiff did not notice any issues with any of the blood draws at PMR.

Here, Plaintiffs have not presented any evidence in the record from which a reasonable jury could have determined causation, but-for causation or proximate causation, without engaging in pure speculation. The only evidence Plaintiff has of a dirty needle stick at PMR is the speculation of Dr. Hull. Plaintiff has failed to establish that but-for negligent acts of PMR, Plaintiff would not have contracted Hepatitis C and would not have needed treatment.

II. Res Ipsa Loquitur

The doctrine of res ipsa loquitur is "a rule of evidence that permits a jury to infer from circumstantial evidence that the defendant is negligent without requiring that the Plaintiff prove defendant's specific negligence. *Martin v. Washington*, 848 S.W.2d 487, 495 (Mo. 1993). The making of a submissible case under res ipsa loquitur creates only a permissible, rebuttable inference of negligence. *Id.* The defendant is not required to introduce evidence to rebut the inference of negligence, and the trier of fact is free to accept or reject the inference, even if the defendant introduces no contrary evidence. *Id.* The burden of proving liability remains, at all times, with the Plaintiff. *Id.*

Res ipsa loquitur is a rule of evidence that permits the jury to infer negligence without direct proof. *Martin*, 848 S.W.2d at 495. The doctrine supplies circumstantial evidence of a breach when the Plaintiff lacks the facts to plead the specific negligent conduct that constituted the breach. *Id.* In effect, res ipsa loquitur carries the Plaintiff over the breach hurdle. *Id.* It cannot, however, leap over the causation hurdle. *Id.*

Missouri courts have declared that the doctrine of res ipsa loquitur applies: when (a) the occurrence resulting in injury was such as does not ordinarily happen if those in charge use due

care; (b) the instrumentalities involved were under the management and control of the defendant; and (c) the defendant possesses superior knowledge or means of information as to the cause of the occurrence. *Sides v. St. Anthony's Med. Ctr.*, 258 S.W.3d 811, 814 (Mo. 2008), quoting *Bass v. Nooney Co.*, 646 S.W.2d 765, 768 (Mo. banc 1983).

Plaintiff has failed to prove "the instrumentalities involved were under the management and control of the defendant." Here, the instrumentality involved was the alleged dirty needle stick. However, Plaintiff has failed to prove PMR exercised management and control over all potential sources of Hepatitis C during the entire relevant period.

As discussed above, there are multiple other potential sources of Hepatitis C including drugs, sexual transmission, piercings/tattoos, and other needlesticks. Additionally, the testimony of Dr. Jordan and Dr. Khan illustrate it would be difficult if not impossible for a dirty needlestick to occur due to the use of universal precautions, training and supervision present.

As there are multiple potential causes of Plaintiff's acute Hepatitis C, Plaintiff failed to establish that PMR had control over the instrumentalities were under the management and control of the defendant.

CONCLUSION

Based on the foregoing facts and case law, Plaintiff will not be able to make either an ordinary negligence case or a case under *res ipsa loquitur*. Accordingly, Plaintiff's cause of action

should be dismissed with prejudice at Plaintiff's cost and for such other and further relief the Court deems just and proper.

HINSHAW & CULBERTSON LLP

By: /s/ Terese A. Drew
Terese A. Drew, #32030
Angela S. McQuage, #63088
701 Market Street, Suite 260
St. Louis, MO 63101-1843
P: 314-241-2600
F: 314-241-7428
tdrew@hinshawlaw.com
amcquage@hinshawlaw.com
Attorneys for Defendants
PHARMA MEDICA RESEARCH, INC.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing document was electronically filed and served to counsel via the Court's e-filing system on this 24th day of May, 2021, addressed to the following attorney(s) of record:

Brian Wendler
Angie M. Zinzilieta
Aaron N. Clite
WENDLER LAW, P.C.
900 Hillsboro, Suite 10
Edwardsville, IL 62025
P: (618) 692-0011
F: (618) 692-0022
wendlerlawpc@gmail.com

Attorneys for Plaintiff

/s/ Terese A. Drew